UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON

UNITED STATES OF AMERICA	)	
	)	
v.	)	
	)	**Case No. 1:19-cr-00016**
INDIVIOR INC. (a/k/a Reckitt Benckiser Pharmaceuticals Inc.) and INDIVIOR PLC	)	

UNITED STATES' RESPONSE IN OPPOSITION TO INDIVIOR'S MOTION FOR ISSUANCE OF PRE-TRIAL RULE 17(c) SUBPOENAS

The United States of America ("United States") opposes the Motion for Issuance of Pre-Trial Rule 17(c) Subpoenas (Doc. 229) ("Mot.") and Memorandum in Support (Doc. 230) ("Mem.") of Defendants Indivior Inc. (a/k/a Reckitt Benckiser Pharmaceuticals Inc.) and Indivior plc (collectively, "Indivior") as follows.

INTRODUCTION

Previously citing *Brady* and Rule 16, and now again under Rule 17, Indivior has sought expansive civil-style discovery in this criminal case, declining to tailor its requests to the Federal Rules of Criminal Procedure and applicable case law. The Rule 17(c) subpoenas Indivior has submitted are facially improper and appear calculated to attempt to delay the trial. The Supreme Court, Fourth Circuit, and this Court have held that Rule 17(c) is not a discovery device, and that Rule 17(c) subpoenas are limited to seeking specific items that are relevant and admissible at trial. By contrast, the Rule 17(c) subpoenas Indivior has submitted pose 53 discovery requests seeking "complete files" of the DEA and six state boards regarding seven physicians, and all documents "reflecting," "supporting," "underlying," and "leading to" supposed "analyses," "conclusions," "determinations," and "reviews" of personnel with the CDC, FDA, NIDA, and SAMHSA.

Indivior has not carried its burden to show (and there is no reason to believe) that the requested documents are relevant and admissible at trial, and seeking discovery of all documents concerning a subject does not satisfy the requirement of seeking specific items. The subpoenas are an abuse of Rule 17(c) and should not be authorized.

FACTS

As the United States explained in prior briefing, it has supplied Indivior with all evidence arguably favorable to the accused known to the prosecution, and Indivior is familiar with this evidence and has explored it. *See* Docs. 146, 227.[1] Nonetheless, by the instant Rule 17(c) subpoenas (Docs. 230-1 through 230-11), Indivior seeks to pose 53 document requests (more if subparts are counted) to 11 federal and state offices for:

- "complete files" of the Drug Enforcement Administration ("DEA") and six state medical and pharmacy boards ("State Boards") regarding seven physicians (Docs. 230-1, 230-6 through 230-11);
- "analysis leading to" supposed conclusions of personnel with the Substance Abuse and Mental Health Services Administration ("SAMHSA") (Doc. 230-2);
- "analysis and review underlying" numerous alleged activities of personnel with the Food and Drug Administration ("FDA") (Doc. 230-3);
- "analysis" and "views" of personnel with the Centers for Disease Control and Prevention ("CDC") (Doc. 230-4); and
- "efforts," "positions," and "statements" of personnel with the National Institute on Drug Abuse ("NIDA") (Doc. 230-5).

[1] The United States incorporates the Facts sections of Docs. 146 and 227 by reference, rather than repeat them here.

Exemplifying the breadth of Indivior's document requests, one of the requests seeks all records reflecting "the support and basis for the FDA's policy . . . to encourage widespread innovation and development of new buprenorphine treatments for opioid use disorder." Doc. 230-3; Mem. at 16. Another seeks all records "relating to the congressional testimony of FDA Commissioner Scott Gottlieb in October 2017 and any other FDA personnel regarding the expanded utilization of buprenorphine treatments." *Id.* Another seeks all records "reflecting NIDA's efforts to collaborate with [Indivior] in and around 1994 to develop buprenorphine products for the treatment of opioid dependence." Doc. 230-5; Mem. at 20. Still others seek all "analysis of and views expressed by" certain CDC personnel "regarding the impact of unit-dose packaging of buprenorphine products on pediatric exposure. . . ." Doc. 230-4; Mem. at 17-18.

The prosecution neither possesses nor intends to use the documents Indivior seeks. The prosecution does not know whether they exist and, if they exist, what they may say or where they may reside within the various offices. Indivior claims to "know" that responsive documents exist, "on account of (1) the agencies' clearly defined roles in the oversight and/or regulation of the controlled pharmaceutical supply chain or (2) the information contained in documents produced by the government in this case or in other publicly available materials." Mem. at 3. The United States does not agree that the foregoing assertion shows Indivior knows whether the documents exist or what they say.

Indivior previously sought similarly broad discovery citing *Brady v. Maryland*, 373 U.S. 83 (1963), and Federal Rule of Criminal Procedure 16(a)(1)(E)(i), demanding that the prosecution search various federal offices. *See* Docs. 118 and 118-1 (Indivior's requests), 146 (United States' response), and 220 (United States Magistrate Judge's Order, which Indivior has appealed to this Court).

For ease of reference, the following chart indicates the scope of each request in the Rule 17(c) subpoenas Indivior has submitted.

Doc.	Recipient	Request	Scope
230-1	DEA	1-7	complete DEA files
230-2	SAMHSA	1-7	records reflecting SAMHSA review
230-2	SAMHSA	8	records reflecting SAMHSA policies
230-2	SAMHSA	9-11	records reflecting SAMHSA analysis
230-2	SAMHSA	12	evidence supporting SAMHSA determination
230-3	FDA	1-2	records reflecting FDA review
230-3	FDA	3	annual assessment reports and related reviews
230-3	FDA	4-7	records reflecting FDA analysis and review
230-3	FDA	8	records reflecting guidance provided
230-3	FDA	9	meeting materials and minutes from meetings or calls
230-3	FDA	10	records reflecting FDA review or analysis
230-3	FDA	11	records reflecting FDA analysis
230-3	FDA	12	records reflecting the support and basis for FDA policy
230-3	FDA	13	records relating to congressional testimony
230-3	FDA	14	records reflecting FDA review and analysis
230-4	CDC	1-4	records reflecting analysis and views of CDC employees
230-4	CDC	5	records reflecting CDC analysis and action
230-4	CDC	6	records reflecting CDC analysis
230-5	NIDA	1	records reflecting NIDA efforts to collaborate with Indivior
230-5	NIDA	2	records reflecting and supporting NIDA position
230-5	NIDA	3	records reflecting and supporting NIDA statement
230-5	NIDA	4	records reflecting and supporting statement of NIDA employee
230-6	Va. DHP	1-2	complete Virginia Dep't. of Health Professions files
230-7	Tenn. HRB	1-2	complete Tenn. Health Related Boards files
230-8	Ky. BMed.	1-2	complete Kentucky. Board of Medicine files
230-9	Ky. BPharm.	1-2	complete Kentucky Board of Pharmacy files
230-10	Penn. BMed.	1	complete Pennsylvania State Board of Medicine file
230-11	Penn. BPharm.	1	complete Pennsylvania State Board of Pharmacy file

LAW AND ARGUMENT

The Rule 17(c) subpoenas Indivior has submitted are facially improper, and Indivior has not carried its burden to show that the subpoenas seek specific items that are relevant and admissible at trial.[2]

A. Legal Standard for Issuance of Rule 17(c) Subpoenas

The purpose of Rule 17(c) is to expedite criminal trials by providing a time and place before trial for the inspection of evidence for use at trial, not to facilitate discovery. *United States v. Richardson*, 607 F.3d 357, 368 (4th Cir. 2010); *see also United States v. Modi*, No. 01-cr-50, 2002 WL 188327, at *2 (W.D. Va. Feb. 6, 2002) (Rule 17(c) "was in no way intended as a means of discovery").

The Fourth Circuit has "emphasized that Rule 17(c) is not a discovery device." *United States v. Caro*, 597 F.3d 608, 620 (4th Cir. 2010) (citing and quoting *United States v. Fowler*, 932 F.2d 306, 311 (4th Cir. 1991) (citing *Bowman Dairy Co. v. United States*, 341 U.S. 214, 220 (1951))). It has also affirmed that a Rule 17(c) subpoena "cannot substitute for the limited discovery otherwise permitted in criminal cases and the hope of obtaining favorable evidence does not justify the issuance of such a subpoena." *Caro*, 597 F.3d at 620.

A party seeking a Rule 17(c) subpoena must show that specific items are relevant and admissible at trial. *United States v. Nixon*, 418 U.S. 683, 699-700 (1974); *Caro*, 597 F.3d at 620. "Relevant" means satisfying the requirements of Rule 401 of the Federal Rules of Evidence, not "relating to." *See United States v. Dixon*, 486 F. Supp. 2d 40, 44 (D.D.C. 2007). Rule 401

[2] If the subpoenas are authorized and served, then the United States reserves the right to move to quash them under Rule 17(c)(2) based on undue burden, or for other reasons. To date, the United States has not fully ascertained the practical burdens the subpoenas could impose on the 11 federal and state offices to which they are addressed (*e.g.*, costs, resources).

provides that evidence is relevant if it has a tendency to make a fact more or less probable and that fact is of consequence in determining the action.

A Rule 17(c) subpoena is improper if used to conduct a fishing expedition. *Nixon*, 418 U.S. at 699-700; *see also Richardson*, 607 F.3d at 368 (the defendant "fails to address the principal deficiency in his subpoena – the lack of specificity [without which he] is merely fishing for evidence that might support his theory, as if he were in the discovery phase of a civil action"). As this Court stated in *Modi*, Rule 17(c) subpoenas cannot be based on defendants' mere hopes of "uncovering something useful to their defense." 2002 WL 188327 at *2.

The court is required to examine Rule 17(c) subpoenas for compliance with the *Nixon* test, and "has a 'responsibility to prevent Rule 17(c) from being improperly used as a discovery alternative to Rule 16.'" *Modi*, 2002 WL 188327 at *2 (quoting *United States v. Beckford*, 964 F. Supp. 1010, 1022 (E.D. Va. 1997)); *see also Fowler*, 932 F.2d at 311 ("The district court aptly observed that the application [for subpoenas *duces tecum*] was little more than a duplication of [the defendant's Rule 16] discovery motion," which the district court had correctly denied).

B. Indivior's Theory of Specificity Would Negate the Specificity Requirement

Indivior contends that the specificity requirement, as established by the Supreme Court in *Nixon*, refers to substantial categories of documents. *See, e.g.,* Mem. at 6 (Indivior contending the specificity requirement is satisfied by seeking complete files on "specific physicians"), 12 (arguing the requirement is satisfied by seeking all analysis and review of a "category of submissions to the FDA"), 18 (asserting the requirement is met by a request for all documents "tied directly to a specific statement"). On the contrary, the specificity requirement refers to identifiable items or sharply drawn groups, not substantial categories; otherwise it would be superfluous, as any document request can be phrased to seek a category. *See, e.g.*, *United States v. Kipp*, No. 3:15-cr-244, 2016 WL 7209581, at *2-3 (W.D.N.C. Dec. 9, 2016) (collecting

cases); *United States v. Ging-Hwang Tsoa*, No. 1:13-cr-137, 2013 WL 5837631, at *2 (E.D. Va. Oct. 29, 2013) (the "subpoenas at issue here, which indiscriminately request 'complete' files, are perhaps 'a paradigmatic example of a fishing expedition') (quoting *United States v. Williams*, No. 1:09-cr-414, 2010 WL 5113106, at *2 (E.D. Va. Dec. 6, 2010)). Indivior's construction of "specificity" to mean "complete files" and "records" on specific subjects and would eviscerate a Supreme Court requirement.

C. Indivior Has Not Carried Its Burden to Demonstrate that the Requested Documents Are Relevant and Admissible at Trial

Indivior's proposed Rule 17(c) subpoenas to the DEA and State Boards seek "[t]he complete file for" each of seven doctors. Docs. 230-1, 230-6 through 230-11; Mem. at 4-5, 20-21. Indivior's theory is that the Superseding Indictment alleges Indivior aided and referred patients to doctors it had identified as engaging in "very careless and clinically unwarranted prescribing behaviors," *see* Doc. 115 at 28 (¶100) (quoting Indivior medical personnel), therefore "any action or inaction" of the DEA and State Boards "as to these physicians, which will be reflected in the requested files, is highly relevant to the question of the propriety of the physicians' prescribing practices." Mem. at 5, 21. Indivior contends that all of the requested documents are admissible as records of regularly conducted activity pursuant to Rule 803(6) of the Federal Rules of Evidence. Mem. at 6.

Indivior's theory of relevancy and admissibility is conclusory and specious. Indivior supplies no (and there is no) reason to believe that every agency action or inaction regarding a doctor makes it more or less probable that the doctor issued clinically unwarranted prescriptions (*i.e.*, is relevant under Federal Rule of Evidence 401 to the issue Indivior has cited), as distinct from reflecting numerous other agency activities and functions. Nor has Indivior provided any reason to believe that all documents in DEA and State Board files regarding a doctor are records

of regularly conducted activity (*i.e.*, are admissible under Federal Rule of Evidence 803(6)) as distinct from emails, memoranda, notes, reports of others, or the like.

Moreover, the allegations in the Superseding Indictment concern Indivior's marketing and patient referrals to doctors whom Indivior medical personnel, not the DEA or State Boards, determined were engaged in "very careless and clinically unwarranted prescribing behaviors." Doc. 115 at 28. Even assuming, *arguendo*, that the DEA or State Boards had information indicating specific doctors were inappropriately prescribing Suboxone, the DEA's or Boards' knowledge would not be material to Indivior's knowledge. The Indictment does not allege Indivior had knowledge of DEA or State Boards activities, and the documents Indivior seeks are ones Indivior claims it does not know. Accordingly, Indivior has not shown that any information that may be in possession of the DEA or State Boards is relevant and admissible at trial.

It is not the United States' burden to rule out the possibility that a DEA or State Board document regarding a doctor, of which Indivior had no knowledge, could be relevant and admissible at trial. Instead, to issue a Rule 17(c) subpoena, Indivior has the burden to show that the documents it seeks are relevant and admissible at trial. Indivior has not carried that burden by seeking "complete files" via a bare assertion that "any action or inaction is highly relevant" and implausible claim that all agency documents are records of regularly conducted activity.

Indivior's proposed Rule 17(c) subpoenas to the CDC, FDA, NIDA, and SAMHSA have still weaker rationales. Indivior argues that requested documents are "a relevant part of the larger story about the treatments Indivior has developed," Mem. at 16, and "relevant to Indivior's defense of its mission to provide effective outpatient treatment to patients struggling with opioid addiction." Mem. at 19. These are mere speculative conclusions about the documents, and do

not relate to any charge or defense, as neither Indivior's "larger story" nor its "mission" is at issue in this case, which concerns the fraud scheme described in the Superseding Indictment.

- Indivior's requests to the NIDA seek documents relating to the development, use of, and access to buprenorphine and other medications to treat opioid addiction, but the use of buprenorphine to treat opioid addiction is not a disputed issue.
- Its requests to the CDC seek documents relating to analysis of whether doctors should offer medication-assisted treatment for opioid use disorder, but this is not at issue either.
- Its requests to the SAMSHA seek documents related to various public policies, but SAMHSA's public policy views are not at issue.
- Its requests to the FDA seek documents relating to the FDA's views on the development of new buprenorphine treatments, but such policies are not at issue.

Furthermore, Indivior does not provide any explanation of how the CDC, FDA, or NIDA documents would be admissible at trial. Indivior does not reference Federal Rule of Evidence 803(6) (records of regularly conducted activity) with regard to them. Accordingly, even if Indivior were to find whatever it is looking for among the reams of CDC, FDA, and NIDA documents it seeks, Indivior has not satisfied the requirement of showing how it would be admitted as evidence at trial.

D. Indivior's Lack of Specificity Should Not Be Rewarded

The number and breadth of Indivior's document requests indicate a strategy to flood discovery recipients and delay the trial. Indivior should not be rewarded for declining to identify specific items and rigorously demonstrate their relevancy and admissibility.

CONCLUSION

Indivior's Motion for Issuance of Pre-Trial Rule 17(c) Subpoenas should be denied.

Respectfully submitted,

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Authority Conferred by 28 U.S.C. § 515

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CERTIFICATE OF SERVICE

I certify that on December 11, 2019, I electronically filed the foregoing Response in Opposition to Indivior's Motion for Issuance of Pre-Trial Rule 17(c) Subpoenas with the Clerk of Court via the CM/ECF system, which will send notification of the filing to all counsel of record in this matter.

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